

REMARKS

I. Status of the Claims

Claims 1-88 were originally filed and later canceled. Claims 89-124 were subsequently added. Claims 93, 97-103, and 107-130 are currently pending under examination.

Claims 93 and 103 are amended to recite that the HER-2/Neu fusion protein does not comprise any portion of a HER-2/Neu intracellular domain other than the HER-2/Neu phosphorylation domain or the fragment of the phosphorylation domain. This recitation is supported by the specification, *e.g.*, Examples 4-13, where various ECD-PD or ECD- Δ PD fusion proteins are described. According to the MPEP, a claim amendment can be properly supported by a feature inherently or implicitly disclosed in the specification. MPEP §2163 I.B. states, "[t]he fundamental inquiry is whether the specification conveys with reasonably clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." In the present case, Examples 4-13 provides several HER-Neu ECD-PD or ECD- Δ PD fusion proteins, some of which include a tag for identification or purification purpose (*e.g.*, a 6 x His tag). Despite of the differences among the fusion proteins, one of skill in the art would clearly recognize that each and every one of the described HER-2/Neu fusion proteins does not include any portion of the HER-2/Neu intracellular domain (ICD) other than the phosphorylation domain (PD) or the fragment of the phosphorylation domain (Δ PD). The lack of non-PD (Δ PD) portions of the ICD is an inherent feature of these fusion proteins. By way of providing detailed description of these fusion proteins, the specification provides sufficient support for the present amendment, because the specification indeed "conveys with reasonably clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention now claimed."

Claims 93 and 103 are also amended to delete the recitation "wherein when the extracellular domain is linked to (the fragment of) the phosphorylation domain by an amino acid linker, the amino acid linker consists of a non-Her-2/Neu sequence." This recitation was added to the claims in Applicants' response filed December 28, 2004, and was subsequently objected to

by the Examiner in the Office Action mailed March 28, 2005, for alleged lack of support and indefiniteness.

The present amendment introduces no new matter and requires no new searches. Its entry is respectfully requested.

II. Claim Rejections

A. 35 U.S.C. §112, Second Paragraph

Claims 93, 97-103, and 107-130 were rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Specifically, the Examiner asserted that the meaning of the term "a non-HER-2/Neu sequence" is unclear. Since the amended claims no longer recite this term, Applicants submit that this rejection is now moot.

B. 35 U.S.C. §112, First Paragraph

Claims 93, 97-103, 107-118, 121, 122, and 124-130 were rejected under 35 U.S.C. §112, first paragraph, for alleged failure to meet the written description requirement. Specifically, the Examiner alleged that the term "a non-HER-2/Neu sequence," introduced by the amendment submitted in Applicants' response filed December 28, 2004, lacks support from the specification. This rejection is also moot, as the amended claims no longer recite this term.

C. 35 U.S.C. §102

Claims 93, 97, 102, 103, 107, 112, 113, 117, and 118 remained rejected under 35 U.S.C. §102(e) for alleged anticipation by Hudziak (U.S. Patent No. 6,015,567). Applicants respectfully traverse the rejection in light of the present amendment.

To anticipate a pending claim, a prior art reference must provide, either expressly or implicitly, each and every limitation of the pending claim. MPEP §2131. The Hudziak *et al.* reference discloses a mutated Her-2/Neu protein, p185^{HER2ΔTM}, which has a 28-amino acid deletion encompassing the entire 22-amino acid transmembrane domain (*see, e.g.*, column 5, lines 40-43). In other words, p185^{HER2ΔTM} does not contain the transmembrane domain but does contain nearly intact intracellular domain (ICD) and ECD of the HER-2/Neu protein (each

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missing three amino acids immediately adjacent to the transmembrane domain). Since the amended claims now recite that the fusion protein does not comprise any portion of the ICD other than PD or Δ PD, the Hudziak reference clearly does not provide this limitation. As such, this reference does not anticipate the pending claims, and the withdrawal of the anticipation rejection on this ground is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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